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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,427	07/05/2005	Thomas Zelinski	12810-00105-US	6584
23416 7590 02/04/2009 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899				
EXAMINER				
HANLEY, SUSAN MARIE				
ART UNIT		PAPER NUMBER		
1651				
MAIL DATE		DELIVERY MODE		
02/04/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/541,427

**Applicant(s)**

ZELINSKI ET AL.

**Examiner**

SUSAN HANLEY

**Art Unit**

1651

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-29 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-21, 23 and 27-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

The election of claims 14-18, 20, 21 and 23 with traverse in the response filed 2/1/08 is again acknowledged. Claims 19, 22 and 24-26 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. New claims 28 and 29 have been added.

Claims 14-18, 20, 21, 23 and 27-29 and the *Alcaligenes* specie under examination.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The term "stabilizing" in line 2 of claim 21 lacks antecedent basis in claim 14.

### ***Claim Rejections - 35 USC § 102***

Claims 14-18, 20, 21, 23, 27 and 29 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yamaguchi et al. (EP 773,297; cited in the IDS filed 9/8/05).

Applicant argues that Yamaguchi fails to disclose each and every claim limitation and that the preamble has not been given its proper patentable weight. Applicant asserts that the terms "preserving and/or storing" are repeated in the body of the amended claims such that said limitation is more than a mere statement of purpose but

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a required limitation. Applicant argues that the aldehyde concentration and/or the alpha-hydroxynitrile is constantly supplied to the reaction mixture and that the supply of the alpha-hydroxynitrile is discontinued. Applicant concludes that Yamaguchi does not teach a method of preserving and/or storing a microorganism having at least one nitrilase activity in an aqueous medium as claimed. Applicant further asserts that the limitations of the newly added claims, a nitrilase of recombinant origin and a period of up to 37 days, are not recited by the prior art reference.

Responding to Applicant's that the preamble has not been given its proper weight especially when the preamble has been incorporated into the body of the claims, the steps practiced by Yamaguchi meet the limitations of the claims. Although Yamaguchi does not expressly disclose that the nitrilase is preserved and/or stored or stabilized, Yamaguchi's method results in said preservation, storage and stabilization because the prior art steps are the same as those claimed. That is, practicing the same method will inherently yield the same result. The mechanism of the process of purification does not bear on the patentability of the claimed process. Further characterization of what occurs in a known method does not impart patentability because the outcome of the method is the same. See *Ex parte Novitski*, 26 USPQ 2d 1389 (BOPA 1993). Hence, the method of Yamaguchi will inherently result in stabilization and/or storage for up to 37 days since Yamaguchi practices the step of the instant invention.

The point of Applicant's argument regarding the aldehyde concentration and/or the alpha-hydroxynitrile is constantly supplied to the reaction mixture and that the supply of the alpha-hydroxynitrile is discontinued is unclear. If this statement refers to

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claims 17 and 23, said claims are still anticipated because the alternative that "or wherein the aqueous medium does not comprise any addition of said cyanide compounds" is still met because there is no limitation as to the length of time that the microorganism/aldehyde composition is free of nitrile.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-18, 20, 21, 23, 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamaguchi et al. (EP 773,297; cited in the IDS filed 9/8/05).

Yamaguchi discloses a process for producing alpha-hydroxyamides or alpha-hydroxy acids by reacting a microorganism having nitrilase activity with a substrate in the presence of a mixture of an aldehyde and prussic acid (synonym for hydrogen cyanide). Yamaguchi teaches that any microorganism that is capable of carrying out the reaction to produce the disclosed product(s) are suitable for carrying out the reaction. Yamaguchi discloses a number of suitable microorganisms (p. 4, [0014] to [0019]) and selects a group of seven particular strains including *Alcaligenes* sp. (BC16-2) for performing the reaction. This group of seven microorganisms is small and well-defined. Yamaguchi teaches suitable aldehydes such as benzaldehyde (page 4, [0020] to p. 5, [0024]), as in instant claims 15 and 18. The concentration of the

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aldehyde is in the range of 0.01 to 1,000 mM, 0.05 to 200 mM or 1 to 50 mM (p. 3 [0009]). The final concentration of 1 to 50 mM partly overlaps the claim range of 0.1 to 100 mM. The disclosed method will result in the preservation and/or storage of the microorganism because Yamaguchi practices the same steps as the claimed method. Hence, the outcome of Yamaguchi's method will naturally result in stabilization and/or storage of said microorganism having nitrilase activity.

Yamaguchi does not disclose that the microorganism is of recombinant origin.

However, because recombinant microorganisms expressing nitrilase were well known at the time of applicant's invention to encompass said microorganisms having nitrilase identical to their non-recombinant counterparts, and to therefore function substantially in the same manner as their non-recombinant counterparts, one of ordinary skill would have been motivated to have a recombinant microorganism expressing the same as substantial equivalents to their non-recombinant counterparts. A holding of obviousness is therefore required.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/  
Examiner, Art Unit 1651

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/Sandra Saucier/

Primary Examiner, Art Unit 1651